

**Dr. Guenther Gapp,
Independent Consultant, Microbiologist
Gapp Quality GmbH, Austria**

For more than six years the microbiologist Guenther Gapp has been working as an independent consultant with different clients and contractors worldwide (50 assignments in USA, India, Brazil, Korea and Europe). In many projects he has been engaged as “Aseptic Processing Expert” in remediation of companies cited with Warning Letters, and in audits, start- up of facilities, training and remediation assignments. In his previous career, Guenther spent 20 years in the pharmaceutical industry as Head of QA/QC Microbiology and as Sterility Assurance Expert and Troubleshooter. During this period he gained in-depth experience in aseptic processing key elements, and has been a subject matter expert in 20 FDA audits. Guenther also created a new sterile risk assessment tool (SPCRA) to identify and reduce the microbial contamination and compliance risk of sterile products, which works out well if the right people are doing the assessment. The publication of this risk assessment tool won him the 2011 PDA Journal of Pharmaceutical Science and Technology Award.

In 2017 Guenther has been member in the PDA Task Force group commenting the upcoming EU Annex 1 revision. Also since 2017 he is member in the recognized PDA Science Advisory Board, and Co-Chair in the PDA Task Force “Isolator Technology in the Pharmaceutical Industry”.

Since 10 years he is trying to improve the current hygiene conditions and aseptic working practices in the local Austrian hospitals, approaching as a worldwide recognized and experienced Hygiene, Disinfection and Aseptic Operations expert. The aim would be to reduce the threatening “nosocomial infection rates” of patients after surgeries. Unfortunately this initiative has not been successful until now because of resistances of the hospital management.

